



ASOCIACION DE
EXPORTADORES DE CHILE A.001 '03 APR -4 A11 :55

April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Registration of Food Facilities Under the Public Health
Security and Bioterrorism Preparedness Act of 2002

The Members and Objectives of the Chilean Exporters Association (Asociación de Exportadores de Chile, A.G. "ASOEX")

These comments are filed on behalf of the Chilean Exporters Association (ASOEX), a trade association whose members account for approximately 85 percent by volume of total exports of fresh fruit and vegetables from Chile to all world markets. A list of the member companies is attached as Exhibit 1.

The Chilean fresh fruit and vegetable export sector generates annual returns of \$1.6 billion FOB. Approximately 9 percent of the total Chilean workforce is employed in growing fruit and vegetables and in service industries related to their exportation to world markets, of which the United States is the largest single destination. In the 2001-2002 season, 679 thousand tons were shipped to the US, accounting for 37.5 percent of total world exports of 1.81 million tons.

One of the primary missions of ASOEX, reaffirmed after the events of September 11, 2001, is to maintain and increase the world leadership position of the Chilean fruit and vegetable industry in assuring the quality and safety of the products exported from Chile to world markets. For this reason, ASOEX is committed to supporting all governmental initiatives that effectively and efficiently guard against threats to the security of the food supply, especially threats of tampering or bioterrorism. With that primary mission in mind, ASOEX has been actively involved in forming partnerships with all government agencies worldwide working toward enhanced security measures. In forming these partnerships, ASOEX has also drawn on its lengthy and successful cooperative agreements formed with several US agencies and their Chilean government counterparts over the last twenty years, as noted below.

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ASOEX urges FDA to specifically provide in its implementing regulations for the integration and reliance upon existing reporting and control requirements and procedures to accomplish, whenever appropriate, the security objectives of the Security and Bioterrorism Preparedness Act of 2002.

Specifically, ASOEX recommends that FDA:

- (1) Rely on existing facility registration and reporting systems, maintained under the supervision of SAG and other agencies of the Chilean Government, that provide all information necessary to comply with the Security and Bioterrorism Preparedness Act of 2002.***
- (2) Integrate all registration and cargo notice requirements with nearly identical information that is required by USDA and Customs.***
- (3) Exempt Chilean fresh fruit and vegetable shipments from reporting requirements that duplicate time-tested and comprehensive systems already in place.***

As described in greater detail below and in attachments to these comments, most, and perhaps all, of the reporting data required by the proposed regulations is already contained in: (1) a registry data base maintained by ASOEX and the Chilean government equivalent of USDA known as SAG; (2) reporting and control procedures administered by ASOEX/SAG pursuant to a cooperative agreement with USDA; (3) security procedures initially adopted and since improved as the result of an agreement reached with FDA after a terrorist threat to the Chilean fruit and vegetable export sector in 1989; and (4) reports provided to U.S. Customs to comply with the new customs regulations requiring advance notice of shipments destined to the United States.

For the last five years, SAG and ASOEX have worked closely with FDA's CFSAN to improve food safety controls and to implement a range of training programs to assure that the safety controls are properly implemented. CFSAN has first hand knowledge of SAG inspection procedures and operational practices as the result of several trips to Chile in connection with these efforts.

As described in Exhibit 2, Procedures for the Exports of Chilean Fresh Fruit and Vegetables to the US Market¹, comprehensive documentation and security measures are applied at each critical control point from the farm to the arrival of produce at port in the United States. These documented control measures serve the twin and overlapping purposes of preventing any break in the "cold chain" (calibrated refrigeration of produce) and unauthorized access to the produce to assure its security. A break in the cold chain compromises the condition of the fruit and thereby diminishes its commercial value upon delivery. The phytosanitary controls were first formalized in 1982 in the form of a Tri-Party Cooperative Agreement among SAG, USDA/APHIS and ASOEX, and were subsequently improved every year after 1982.

To administer the Cooperative Agreement and other such arrangements in South America, USDA/APHIS staffs a permanent office in Chile. Under the "Operational Workplan, Preclearance

¹ The document was prepared and filed on December 30, 2002 to support exemption requests from the 24 hour advance manifest filing requirements contained in 19 C.F.R. §4.7(b)(2) filed by ocean carriers of Chilean produce with U.S. Customs. In January 2003, U.S. Customs granted the exemption request for all break bulk carriers of Chilean produce based on the information provided. We have not included the voluminous attachments with these comments, but can make them readily available to FDA upon request.

Program,” all producers and all facilities that process and package produce destined for the United States must be registered. Attached as Exhibit 3, are copies of the registration and compliance forms required by the Workplan. ASOEX urges FDA to expressly provide in its regulations that the registration forms required by this or a comparable USDA approved and supervised Work plan satisfy the facility registration requirements. Further, ASOEX urges FDA to rely upon the existing USDA/APHIS registration database to avoid unnecessary duplication of reporting and registration.

The Cooperative Agreement further requires that all produce packages shipped to the U.S. market be labeled with: (1) the name of the exporting company; (2) country of origin; (3) the species, variety and size of the produce; (4) identification (usually by code) of the packing facility; (5) province and locality or origin; and (6) the date of shipment. The information contained on the package permits complete traceability of the product.

As noted, following the terrorist threat to Chilean produce in March 1989, ASOEX and SAG in cooperation with USDA and FDA implemented a series of security measures, described at length in Exhibits 2 and 4, that were applied to the entire production and transportation chain from farm to port of embarkation from Chile to port of arrival in the United States. These measures have been improved and reviewed each year since, and were significantly enhanced following the September 11, 2001 terrorist attacks in the United States. Further, the security measures applied to Chilean produce shipments have been fully integrated with and enhanced by the Chilean industry’s development and implementation of a Program of Good Agricultural Practices (GAPs).

All Chilean fruit shipped to the United States departs from the Chilean ports of Valparaiso, San Antonio, Coquimbo (together accounting for 92%); Caldera, and in a few cases from Lirquen or Talcahuano (together accounting for the remaining 8%). All Chilean port facilities are under the supervision and control of the Chilean government, more specifically the Chilean military. Each port has 24-hour security personnel present, with access strictly limited to authorized personnel. The Chilean fruit and vegetable export sector has taken a clear lead in the world in the application of security measures to all aspects of production and shipment of produce.

All Chilean fruit transported by ocean carriers travel in sealed holds or containers. Each carrier implements security measures to prevent access to the product for the dual purposes of maintaining the cold chain and preventing tampering with the product.

Chilean produce enters the United States at leased and secured terminals in Philadelphia, Los Angeles, Wilmington (Delaware), San Diego, Long Beach, Seattle, New York, Miami, Camden (New Jersey), Port Hueneme (California), Oakland, Baltimore, Charleston, Elizabeth, Everglades, Houston, Portland and Wilmington (North Carolina). The U.S. ports of arrival are also under 24-hour guard with access limited to authorized individuals.

USDA officials permanently on assignment in Chile prepare within 48 hours after a vessel has embarked for the United States, a cargo plan for the specific cargo on each vessel. The cargo plan includes; (1) the name of the vessel; (2) the loading port; (3) date of departure; (4) port of departure; (5) port(s) of destination; (6) date of arrival; (7) total number of boxes/pallets of fruit for each species; and (8) location of types of fruit in the vessel. The cargo plan also details the phytosanitary condition of the fruit. The cargo plan is transmitted electronically to USDA officials at the U.S.

ports of arrival. ASOEX recommends that FDA rely upon, and accept, the cargo plan for purposes of complying with the requirements of the Security and Bioterrorism Preparedness Act of 2002.

Technical Comments

The technical comments that follow are relevant only if FDA does not elect to rely upon existing reports and procedures as complying with the requirements of the Security and Bioterrorism Preparedness Act of 2002.

1. Registration of Food Facilities

- a. **Facility Registration Form:** The form should be made available in Spanish to avoid misreporting.
- b. **Registration Exemptions:** It is not clear if foreign facilities must be registered when the packaging of product takes place on the farm. If FDA relies upon and accepts the existing registration system maintained for Chilean entities, it will have a complete, coherent and well-understood method free of this type of ambiguity.
- c. **Agent identification:** Packing facilities in Chile owned and operated by producers do not have agents in the United States. Instead, the product packed by a producer is delivered to an exporter, which may then ship the product to one or more receivers in the United States. Similarly, an exporter company that operates a packing facility may also ship to one or more receivers in the United States. Again, this potential reporting problem underscores the importance of relying upon the existing and well-understood registration system as complying with the registration requirements of the Security and Bioterrorism Preparedness Act of 2002.
- d. **Procedure for updating information:** The regulation does not establish a procedure for new facilities to register after December 12, 2003. Again, the existing registration system covers this contingency.

2. Prior Notice of Imported Food

- a. **Prior Notice Submission:** The proposal allows only for the identification of one manufacturer per shipment. In Chile, one shipment can be sourced from multiple producers and packing and storage facilities. The current electronic cargo plan and U.S. Customs notices contain all necessary information for compliance with the Security and Bioterrorism Preparedness Act of 2002.
- b. **The section corresponding to grower** should include the registration of names or codes of the producers in order to provide immediate traceability through associated importers and exporters in the event of an emergency situation. The existing system in Chile allows immediate access to such information.

- c. Time of Prior Notice: An 8 hour advance notice requirement is not practical for air shipments. Many air shipment flights are less than 8 hours in length. Further, cargo planes in Chile are in short supply, which results in some shipments being made on passenger planes when space becomes available. In any event, the advance notice requirement is duplicative of existing Customs regulations. The two agencies should rely on the same report to avoid duplication of efforts.

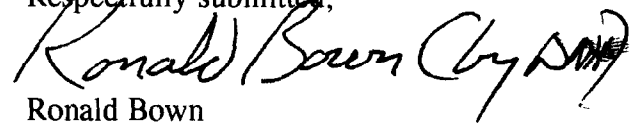
CONCLUSION AND RECOMMENDATIONS

ASOEX strongly recommends that FDA:

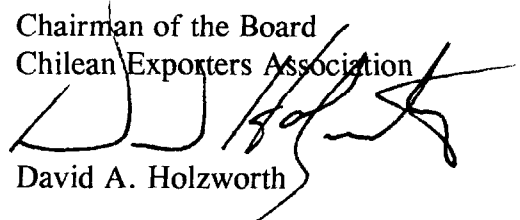
- (1) Rely on existing facility registration and reporting systems, maintained under the supervision of SAG and other agencies of the Chilean Government, that provide all information necessary to comply with the Security and Bioterrorism Preparedness Act of 2002.
- (2) Integrate all registration and cargo notice requirements with nearly identical information that is required by USDA and Customs.
- (3) Exempt Chilean fresh fruit and vegetable shipments from reporting requirements that duplicate time-tested and comprehensive systems already in place.

ASOEX is committed to working with all United States agencies to enhance anti-terrorism measures, and would be pleased to discuss and elaborate upon the materials submitted with these comments to achieve these goals in the most cost-effective way possible.

Respectfully submitted,


Ronald Bown

Chairman of the Board
Chilean Exporters Association


David A. Holzworth

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Chilean Exporters Association